IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE NATIONAL PRESCRIPTION OPIATE LITIGATION This document relates to: Case No. 1:18-op-45817-DAP COBB COUNTY Plaintiff, vs. PURDUE PHARMA, ET AL., Defendants.	MDL No. 2804 Case No. 17-md-2804 Judge Dan Aaron Polster

Expert Report of Stefanie Ferreri, PharmD, BCACP, FAPhA
June 24, 2024

I was asked to evaluate and provide an opinion regarding Publix Super Markets Inc.'s ("Publix") policies, procedures and practices regarding the dispensing of opioids from 2006 to approximately 2021. I reviewed documents, deposition testimony, and interviewed Publix pharmacists in order to examine and provide my professional opinion regarding Publix's corporate conduct regarding the maintenance of effective controls against the diversion of opioids and how Publix's corporate conduct aligned with the usual and customary practice of other community or retail pharmacies and the industry expectations and standard of care.

1. Summary of Opinions

Publix met its obligations to institute effective diversion control programs and maintained effective controls against the diversion of controlled substances during the applicable time period. Publix's policies and procedures were appropriate to support their pharmacists' exercise of corresponding responsibility in evaluating, filling, and dispensing opioid prescriptions. Publix operated consistent with the pharmacy practice standard of care, and consistent with my own experience in the pharmacy industry.

2. Background, Expertise, and Qualifications

I am a distinguished professor of pharmacy practice and Chair of the Division of Practice Advancement in Clinical Education at the UNC Eshelman School of Pharmacy at the University of North Carolina at Chapel Hill. I have been a licensed pharmacist since 1997. I practiced in community pharmacies in Connecticut and North Carolina from 1997-2013. I started my career as a student pharmacist/intern working with a national corporate chain. Once I graduated, I worked as a pharmacist at the same chain and reciprocated my Connecticut license to North Carolina where I continued to practice with the same chain. During my transition to North Carolina the chain was buying out another chain and I served as one of the pharmacy trainers on the software system. In addition to practicing at the national corporate pharmacy chain in two states, I was also a resident pharmacist at an independent pharmacy in rural eastern North Carolina. Once I completed my doctorate in pharmacy, I practiced at a regional chain pharmacy in North Carolina while beginning my academic career at UNC. In addition, I have worked as an inpatient pharmacist at Duke University Medical Center in Durham, NC and the UConn Health Center (John Dempsey Hospital) in Farmington, CT.

I received my Bachelor of Science (BS) in Pharmacy from the University of Connecticut. A BS in pharmacy was a five-year degree in which students were required to complete two years of undergraduate studies and three years of pharmacy studies. The last year of the pharmacy program required training in 3 practice areas – community, hospital, and direct patient care. I went on to further my education by obtaining my Doctor of Pharmacy (PharmD) from Campbell University in North Carolina. The PharmD provided me with an additional year of pharmacy coursework and an additional year of training. Since 2000, the PharmD is the entry level degree for all pharmacists in the United States.

As a pharmacist licensed in two states, I was required to pass a national certification exam called the North American Pharmacist Licensure Examination (NAPLEX). I was also required to pass the law exams, the Multistate Pharmacy Jurisprudence Examination (MPJE) for each individual state. This is required for all licensed pharmacists in the United States. Once I became licensed and started working as a pharmacist, I performed typical responsibilities of a pharmacist working in a community pharmacy setting. These include preparing and dispensing prescriptions and processing insurance claims for those prescriptions. I advised patients on the appropriate use of nonprescription medications. I counseled patients on their medications, proactively identified medication related problems and advised on appropriate medication therapy to patients and their primary care providers. In addition to patient care responsibilities, I also oversaw and managed the workflow in the pharmacy. This included inventory management, technician oversight, and engaging with upper management of the company. All pharmacists who graduate from an accredited school of pharmacy and who pass the licensure exams are qualified to do the aforementioned activities.

In my current position at the UNC Eshelman School of Pharmacy, I study and teach about practice changes in the community pharmacy environment. Community pharmacy is sometimes known as retail pharmacy. It is the most common type of pharmacy that allows the public access to their

medications and advice about their health. Everything I do begins and ends with the patient in mind. My research focuses on implementing new policies or patient care services into practice. I use principles from implementation science which seeks to close the gap between what we ***know*** and what we ***do*** by identifying and addressing the barriers that slow or halt the uptake of proven health interventions and evidence-based practices. I have authored or co-authored five book chapters, approximately 90 peer-reviewed articles, 36 funded grants, more than 100 abstracts and poster presentations, and spoken at least 60 professional and academic events about topics in the field of pharmacy, focusing on dispensing activities in community or retail pharmacies. Approximately half of those writings and engagements have addressed the evolving standard of care for community pharmacists. These writings and engagements often address incorporating patient care services into the dispensing workflow. This work encompasses the general practices and standards of care for dispensing controlled substance prescriptions.

My "work on the bench" as a community pharmacist from 1997-2013 informs my current implementation science research. Although I no longer actively practice on the bench, I have weekly and, at times, daily interactions with community pharmacy colleagues. These communications occur with pharmacists from independent and chain pharmacists throughout the country to inform myself of the current practices of dispensing pharmacists. These interactions are essential to both my research work as well as my responsibilities teaching the next generation of community pharmacists. Because of this, I am still engaged in the evolving standard of care in community practice. For example, at UNC, my team of researchers and I partnered with 250 community pharmacists to develop and implement a collaborative care model to integrate community pharmacists into medical home care teams, which was later funded by the Center for Medicaid and Medicare and then expanded to nearly 4000 pharmacies across the country. Another way I stay informed about changes in clinical practice is through active involvement in professional organizations, including the American Pharmacists Association (APhA), the American College of Clinical Pharmacy (ACCP), American Association of College of Pharmacy (AACP), among others.

Over the course of my career as a clinical professor and post-graduate educator and director, I have trained thousands of new pharmacists. I have coordinated, developed, and taught courses for pharmacists about the foundations of patient care, including teaching them about evaluating prescriptions to determine if they are illegitimate and interacting with patients before dispensing medicines.

I have also served as a preceptor from 2001-2012 and later director of UNC's Accredited Community Pharmacy Residency Program from 2004-2015. As a preceptor, I was responsible for providing students and new pharmacist graduates on the job training in a pharmacy with the intent of providing them with the knowledge of how the principles they learned in the classroom practically apply when dispensing prescriptions, including opioids. In my role as director, one of my responsibilities was to select pharmacies that would provide preceptors. A requirement for being selected as a host pharmacy was the pharmacy and its pharmacists complied with the standard of care.

In 2014, I developed and served as the founding director of the Community Pharmacy Research Fellowship at UNC, which trains graduates for academic research roles. The following year, I developed and directed the Independent Pharmacy Ownership Residency at UNC, which trains future independent pharmacy owners. Part of the skills-based training for residents is to teach them about the standards of practice expected of community pharmacists. To provide this training I had to maintain a knowledge of trends, standard of care, and current experiences of dispensing pharmacists throughout the country, including an understanding of the industry requirements, expectations and typical practices regarding the dispensing of controlled substances. I was recognized with a Distinguished Achievement Award by the American Pharmacists Association for the development of these programs.

I have received national funding for multiple research projects from the CDC related to de-prescribing opioid use in adults who are 65 or older. A pharmacist's approach focuses on educating healthcare providers on how to de-prescribe opioids for patients for whom the medicines pose risks, with the specific goal of reducing falls, as well as educating patients about the risk of falls and injury posed by their medication. While pharmacists do not prescribe medications, they can play a part in facilitating intervention by engaging with providers and patients. This work has led to the development of a toolkit that is disseminated by the CDC on their website. I also study how community pharmacists optimize medications for patients in the community pharmacy setting.

A detailed history of my professional experience and qualifications is contained in Appendix A.

3. Standards Governing the Pharmacists Role in Dispensing Controlled Substances

A pharmacist's primary directive with respect to dispensing controlled substances is to not fill prescriptions known or that should have been known to the pharmacist to be illegitimate.

The Federal Controlled Substances Act ("CSA") sets forth certain requirements for proper prescribing and dispensing of controlled substances. In order for a controlled substance prescription to be valid, it "must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice."[1] As explained by the DEA Pharmacists' Manual, "[t]he practitioner is responsible for the proper prescribing and dispensing of controlled substances, but a corresponding responsibility rests with the pharmacist who fills the prescription."[2] Pharmacists are "required to exercise sound professional judgment, and to adhere to professional standards, when making a determination about the legitimacy of a controlled substance prescription."[3]

[1] 21 CFR 1306.04(a).

[2] Drug Enforcement Admin., Pharmacists' Manual (2022), at 39, available at https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-046R1)(EO-DEA154R1)_Pharmacist%27s_Manual_DEA.pdf.

[3] *Id*. at 41.

When exercising this professional judgment, a pharmacist brings to bear years of education and training, not only from their schooling but through hands-on experience and an internship model commonly employed in the industry. A pharmacist's professional judgment takes into account the totality of the circumstances each time a prescription is evaluated.

A. Using Professional Judgment to Evaluate Prescriptions to Determine if They Are Illegitimate

Consistent with this corresponding responsibility, the primary role of a community pharmacist is to ensure medications are safe for patients from the dispensing perspective. When pharmacists have questions about whether a medication is appropriate for a patient, they use their professional judgment and communicate with the patient and, when necessary, their prescriber to obtain more information. Every pharmacist upon graduation takes an oath whereby they agree to "apply our knowledge, experience, and skills to the best of our ability to assure optimal outcomes for all patients."[4] Pharmacists take this responsibility seriously.

In community pharmacy, pharmacists use their professional judgment to fulfill their corresponding responsibility when evaluating a prescription for a controlled substance. More specifically, a pharmacist must use his or her professional judgment in determining whether an opioid prescription was written for an illegitimate purpose and whether it was issued outside the scope of practice of the prescriber. In many cases a community pharmacist is familiar with the prescribers in their area who regularly write such prescriptions. Community pharmacists often see the same prescribers daily writing prescriptions for their patients. There are instances when community pharmacists identify a prescriber that they are not familiar with. This prescriber may be new to the community, or they may not be part of the community – they may be a long distance from the pharmacy location. Where a prescriber is not part of a pharmacist's community, a pharmacist acting within the usual and customary standard of care will likely check to see what the prescription is for and will assess if that prescription makes sense to be written by that prescriber. For example, if the prescription is written by an oncologist affiliated with the nearest health care facility to treat cancer patients which is known to be a long distance away, the distance in that case is not a reason to do any further investigation of the prescription, or to refuse to fill the prescription. However, if a prescription is presented from a dentist who is not in the pharmacist's community and that dentist is writing a prescription for birth control, it will be questioned, and a pharmacist may decide to not fill the prescription. Pharmacists are aware of what prescribers and health care resources are in their communities. When they fill a prescription, they are taking this into consideration to determine whether the prescription is legitimate.

B. How a Pharmacist Develops and Employs Their Professional Judgment

[4] American Pharmacists Association, Oath of a Pharmacist (Nov. 2021), https://www.pharmacist.com/About/Oath-of-a-Pharmacist.

The CSA emphasizes a pharmacist's application of their professional judgment when determining the legitimacy of a controlled substance prescription. Further, each pharmacy and pharmacist is required to comply with the legal standards in their jurisdiction, as well as guidance provided by the state's Board of Pharmacy. In order to comply with these standards, pharmacists receive extensive schooling, are required to pass comprehensive examinations, receive on the job training, and are must complete continuing education throughout their careers.

i. Education, The Five R's, and Patient Care Processes

All pharmacy schools teach their students the foundational principles necessary to properly apply their professional judgment. Pharmacists are taught that they must always exercise sound professional judgment based on their clinical knowledge and data available at the time of dispensing when deciding about the legitimacy of a controlled substance prescription. All pharmacists are taught that if they knowingly dispense a controlled substance not issued for a legitimate medical purpose, they may be prosecuted and could lose their professional license.

To help reduce the risk of medication errors, pharmacists are taught during pharmacy school the "Five Rights of Medication Administration." Also known as the "Five R's", these principles help to ensure the right drug, right dose, right route, and right patient, at the right time. This is engrained and practiced during pharmacy school, and it becomes a part of who a pharmacist is once they are licensed practitioners. In fact, one of Publix's employees referenced this language in his testimony.[5] Pharmacists are typically the last health care professional that a patient sees when they have an ailment. Once a patient comes to the pharmacy to receive their medication, they have, at a minimum, seen a nurse and a physician (or another prescriber) in another setting. They are sent to the pharmacy to pick up the medication that was prescribed to them. The pharmacist's job is to make sure that a prescription was prescribed by a licensed health care provider and is appropriate for that patient based on the information available to the pharmacist, such as the patient's other medication history. Pharmacists are one member of the larger health care system to take care of a patient and ensure their safety.

In the community pharmacy setting, pharmacists do not typically have access to the electronic health care record which contains the patient history and diagnosis. Additionally, because laws do not require prescribers to write a diagnosis or an indication on a prescription, when necessary, pharmacists are taught to rely on their relationships with the patients to obtain this information. Pharmacists use the clinical knowledge they learn in pharmacy school and any knowledge obtained through continuing education (CE) requirements to stay up to date on proper dosing of medications.

When the pharmacist fills a medication, they follow the pharmacists' patient care process.[6] This process is taught in pharmacy school and is part of the accreditation standard for pharmacy

[5] Deposition of Fred Ottolino ("Ottolino Dep.") at 33:12-18.

[6] Joint Commission of Pharmacy Practitioners, Pharmacists' Patient Care Process (May 29, 2014), https://jcpp.net/patient-care-process/.

education. The Joint Commission of Pharmacy Practitioners' description of each of the five steps of the process is set forth below.

- **Collect**
  The pharmacist assures the collection of necessary information about the patient in order to understand the relevant medication history and clinical status of the patient. Information may be gathered from the patient and other health care professionals. This process includes collecting, where relevant and appropriate:

  - A current medication list and medication use history for prescription and nonprescription medications, herbal products, and other dietary supplements.
  - Relevant health data that may include medical history, health and wellness information, biometric test results, and physical assessment findings, depending on the specific medication and patient at issue.
  - Patient lifestyle habits, preferences and beliefs, health and functional goals, and socioeconomic factors that affect access to medications and other aspects of care.

- **Assess**
  The pharmacist assesses the information collected and analyzes the clinical effects of the patient's therapy in the context of the patient's overall health goals in order to identify and prioritize problems and achieve optimal care. This process includes assessing:
  - Each medication for appropriateness, effectiveness, safety, and patient adherence.
  - Health and functional status, risk factors, health data, cultural factors, health literacy, and access to medications or other aspects of care.
  - Immunization status and the need for preventive care and other health care services, where appropriate.

- **Plan**
  The pharmacist develops an individualized patient-centered care plan in collaboration with other health care professionals and the patient or caregiver that is evidence-based and cost effective. This process includes establishing a care plan that:
  - Addresses medication-related problems and optimizes medication therapy.
  - Sets goals of therapy for achieving clinical outcomes in the context of the patient's overall health care goals and access to care.
  - Engages the patient through education, empowerment, and self-management.
  - Supports care continuity, including follow-up and transitions of care as appropriate.

- **Implement**
  The pharmacist implements the care plan in collaboration with other health care professionals and the patient or caregiver. During the process of implementing the care plan, the pharmacist:
  - Addresses medication- and health-related problems and engages in preventive care strategies, including vaccine administration.
  - Initiates, modifies, discontinues, or administers medication therapy as authorized.
  - Provides education and self-management training to the patient or caregiver.

- Contributes to coordination of care, including the referral or transition of the patient to another health care professional.
- Schedules follow-up care as needed to achieve goals of therapy.

- **Follow-up: Monitor and Evaluate**
  The pharmacist monitors and evaluates the effectiveness of the care plan and modifies the plan in collaboration with other health care professionals and the patient or caregiver as needed. This process includes the continuous monitoring and evaluation of:
  - Medication appropriateness, effectiveness, safety and patient adherence through available health data, biometric test results, and patient feedback.
  - Clinical endpoints that contribute to the patient's overall health.
  - Outcomes of care including progress toward or the achievement of goals of therapy.

ii. Pharmacist Licensure

Pharmacists must meet stringent requirements in order to become licensed. In Georgia, applicants applying for licensure must (1) complete an application, (2) have attained the age of majority, (3) be of good moral character, (4) have graduated and received a professional degree from a college or school approved by the Board, (5) have completed an internship program approved by the Board, and (6) have successfully passed examinations approved by the Board and have paid the requisite fee.[7] The years of coursework, study, training, and preparation pharmacists undergo in order to obtain licensure is the foundation of their understanding and interpretation of the applicable rules governing pharmacy practice. Further, the licensure process ensures that pharmacists have adequate knowledge and training to begin practicing and using their professional judgment to assess prescriptions.

iii. Pharmacist Training and Experience

Pharmacists receive training during their education and internships, as well as on-the-job training once they are licensed and begin working at a pharmacy. This training and experience feeds into a continual process of refining a pharmacist's professional judgment. During pharmacy school and when I began working as a community pharmacist, I was taught to identify illegitimate prescriptions.

The bulk of a pharmacist's formal training is accomplished during school and in preparing for licensure exams. This is supplemented by on-the-job learning and ongoing education. Regardless of the time spent in the field, a pharmacist joining a company will customarily be onboarded to company policies and procedures at the time of hire. However, retail pharmacy companies do not train pharmacists in medication therapies or pharmacy law. This is a baseline expectation at point of hire and is verified with the state board of pharmacy. As long as a pharmacist maintains their license and meets continuing education (CE) requirements, they are able to practice

[7] Ga. Comp. R. & Regs. R. 480-2-.01.

pharmacy. Passing the national and state board exams deems a pharmacist eligible to practice pharmacy.

A pharmacist receives training in school to know how to identify forged and/or illegitimate prescriptions. All schools are required to have a pharmacy law and regulatory affairs course. This is mandated by the Accreditation Council for Pharmacy Education.[8] In this accreditation standard, schools must teach federal and appropriate state-specific statutes, regulations, policies, executive orders, and court decisions that regulate the practice of pharmacy, including the mitigation of prescription drug abuse and diversion. During my education we had guest speakers in our law class who were former addicts who shared with us ways they manipulated the health care system through forgeries and fraud obtain controlled substances. We also had pharmacists present in our course who had their license revoked because they knowingly dispensed illegitimate prescriptions. We had the executive director of the board of pharmacy speak in our class to emphasize the necessity of following federal and state laws for dispensing controlled substances. Our preceptors during our internship programs reviewed the material we learned in the classroom and applied it to the real-world practice prior to us having to do this as a licensed pharmacist. These types of experiences are typical for all pharmacists. Controlled substance education and learning how to identify a forged prescription is a repetitive part of the pharmacy curriculum. A pharmacist is taught to be on high alert and double, and even triple check, controlled substance medications before signing off on them with their license. All pharmacists, through their education, know this is extremely important as a health care professional.

In addition to a pharmacist relying on their education and training to verify whether a prescription is legitimate, pharmacists may also use other reliable sources in practice to stay educated on the ever-evolving practice of pharmacy. This includes accessing materials provided by the relevant Board of Pharmacy(s), the DEA, NABP, CDC, American Pharmacy Association, and the relevant State Pharmacy Associate(s).

iv. ***Pharmacists' Continuing Education***

Pharmacists are required to complete 30 hours of continuing education (CE) every 2 years to maintain their license in Georgia, which is similar to requirements in other states.[9] CE is one way pharmacists keep up with changes in pharmacy practice. Many companies offer their employees CE as a workplace benefit, including Publix. The programming is relevant to practice trends, and it has the added benefit that it is practical to the company's work environment.

It is industry standard to follow the Accreditation Council for Pharmacy Education (ACPE) Continuing Education Requirements when obtaining yearly CEs. This Provider Accreditation

[8] Accreditation Council for Pharmacy Education, Continuing Education Provider Accreditation, https://www.acpe-accredit.org/pdf/Standards2016FINAL2022.pdf.

[9] Ga. Comp. R. & Regs. R. 480-3-.03.

Program[10] is designed to assure pharmacists, boards of pharmacy, and other members of pharmacy's community of interests, of the quality of continuing pharmacy education programs. The purposes of the ACPE Continuing Education Provider Accreditation Program are to:

- Assure and advance the quality of continuing pharmacy education, thereby assisting in the advancement of the practice of pharmacy.
- Provide pharmacists with a dependable basis for selecting accredited continuing education experiences.
- Provide a basis for uniform acceptance of continuing education credits among the states.
- Provide feedback to providers about their continuing education programs through periodic comprehensive reviews and ongoing monitoring activities with a need toward continuous improvement and strengthening.

There are industry trade organizations, national and state pharmacy associations, and governing bodies that provide ACPE accredited CE materials. Industry trade organizations usually provide trade journals with reputable sources of CE information. One such journal is Drug Store News. This journal is typically provided to pharmacists at no cost and the journal also has free CEs. Another is Pharmacist's Letter. This resource is like the Medical Letter, which is used by practicing physicians. The Pharmacist's Letter is the resource trusted by more than 200,000 pharmacists for staying current on medication recommendations and taking and tracking CE.[11]

C. Opioid Prescribing and Dispensing Standards from the Early 2000s to Present

Health care is a field that constantly changes. Pharmacists are taught how to keep up with those changes. A pharmacists' education teaches them that pharmacy is a profession where you must be committed to life-long learning.

A relevant example is the concept that pain is the "5th vital sign." In the 1990s and early 2000s, it was customary practice to be taught that mantra. Students were taught that pain was undertreated, and that pain should be considered a vital sign to be evaluated on all patients, just like blood pressure and temperature. The perception of pain and the proper treatment of pain has continued to evolve over time. Pharmacists learn about these changes in the pain practice guidelines through industry publications, state board of pharmacy communications, CE requirements and from conversations with pharmacist colleagues.

As a community pharmacist, I dispensed Schedule II-V controlled substances. In dispensing those prescriptions, I followed the rules and regulations that I was taught in pharmacy school, through my CE requirements and on my board exams to ensure that the prescriptions I dispensed were legitimate and not contraindicated by the patient's other medications or known allergies. As stated above, during the mid-2000s, pharmacists were taught that pain was historically

[10] Accreditation Council for Pharmacy Education, Continuing Education Provider Accreditation, https://www.acpe-accredit.org/pdf/Standards2016FINAL2022.pdf.

[11] Pharmacist's Letter, https://pharmacist.therapeuticresearch.com/Home/PL.

undertreated, and if a prescriber determined that their patient needed opioids to treat their pain, pharmacists trusted the prescriber's judgment in choosing the best treatments to treat their patient. Since pharmacists were taught about pain being the 5th vital sign, they were following their responsibilities to take care of the patient in pain and to dispense legitimate prescriptions. It was not until June 2016 that the American Medical Association removed pain from being considered a vital sign.[12]

i. Evolving Industry Custom and Practice to Evaluate Opioid Prescriptions for Legitimacy

Until approximately 2010-2012, it was the general belief in the industry that forgeries and fraud were the main drivers of illegitimate opioid prescriptions leaving pharmacies. Pharmacists followed DEA regulations to ensure controlled substances were being properly ordered and accounted for during inventory. They also conducted weekly pill counts to ensure accuracy. There were policies and procedures in place to address when a pill count or inventory was off at the store level. Pharmacists were concerned with ensuring compliance with DEA regulations and avoiding diversion at the store level. The custom and practice among pharmacists and pharmacies at that time was to focus on preventing employee and non-employee theft and fraud.

Around 2012, the pharmacy industry became more aware of and learned through law enforcement activities, regulatory activities, industry publications, and continuing education that illegitimate prescriptions could present in ways less concrete than fraud or forgery. Any time pharmacists took an ACPE CE training related to opioids, case examples were shared to provide awareness of creative ways some patients were seeking controlled substances for illegitimate purposes. Pharmacists also began using the term "red flag" more commonly to refer to characteristics of a prescription that could indicate a patient is seeking to obtain controlled substances for illegitimate purposes.

Another relevant example is the change in schedule for hydrocodone combination products. I learned that this was a Schedule III controlled substance throughout my education and my early career. In 2014 the DEA changed this to Schedule II, indicating that hydrocodone combination products have a higher abuse risk than originally thought. Pharmacists typically learned about this schedule change by reading Board of Pharmacy announcements, through changes in the ordering process in the pharmacy, and through CE requirements.

It is important to keep in mind that even as the health care industry has confronted the challenge of dealing with opioid diversion and misuse, doctors continue to prescribe these helpful medications to patients when appropriate, and pharmacists continue to dispense them today for legitimate reasons. Pharmacies have received pushback from medical organizations for second-guessing prescriptions before filling them. For example, in its 2020 Opioid Task Force Progress Report, the American Medical Association criticized "pharmacy chains . . . and state laws [that]

[12] Pain News Network, AMA Drops Pain as Vital Sign (June 16, 2016), https://www.painnewsnetwork.org/stories/2016/6/16/ama-drops-pain-as-vital-sign.

continue to inappropriately use arbitrary guidelines to restrict access to legitimate medication that some patients need to help manage their pain."[13]

a. "Red Flags" and Their Role in Dispensing

Pharmacists are used to dealing with "red flags" for medications in health care. The term "red flag" was used years before it was associated with opioids. For example, it is well known that when hypertension (high blood pressure) medications and nonsteroidal anti-inflammatory medications (NSAIDs), such as ibuprofen or naproxen, are taken together, they can have a potential harmful effect on a patient's kidneys. Unmonitored use of the two together could lead to acute or chronic kidney failure. When a patient presents to the pharmacy to fill an NSAID medication and they are already taking a high blood pressure medication, a "red flag" should go up for the pharmacist, causing the pharmacist to pause and determine whether it is appropriate to dispense the NSAID. The pharmacist should obtain more information, if necessary, and then use his or her professional judgement before making the dispensing decision. At any time, if a pharmacist suspects that patient safety may be at risk, they will pause to reassess. This is an example of how pharmacists resolve a red flag while filling prescriptions for patients.

In the context of opioid medications and other controlled substances, the term "red flag" is often used to indicate that a patient may be seeking controlled substances for a non-legitimate medical purpose. The DEA provides guidance on potential diversion from patients in its Pharmacists' Manual and other quick reference guides.[14] For example, one of its quick reference guides regarding preventing diversion identifies "Possible Red Flags" regarding patients and practitioners, but also explicitly states that these red flags are not intended "to reduce or deny the use of controlled substances where medically indicated" and that "[d]oing one or more of these does not make prescribing illegal. It is the totality of the circumstances."[15]

There is no one definitive list of "red flags" applicable to Schedule II prescription medications, but rather an evolving set of guidelines, examples, and general categories or types of "red flag" factual scenarios that have developed over time as possible indications that a controlled substance prescription is not legitimate. As stated by GDNA Director Troughton, red flags are not "the rule or the law," but rather "an educational tool."[16] Additionally, not all red flags are applicable or carry the same weight in each community or context. Evaluating and balancing the assessment of "red flags" in the context of dispensing each prescription is part of the exercise of the pharmacist's corresponding responsibility.

Possible Signs of an Illegitimate Prescription:

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[13] Am. Med. Ass'n., Opioid Task Force 2020 Progress Report: Physicians' progress toward ending the nation's drug overdose and death epidemic (2020), available at https://www.ama-assn.org/system/files/2020-07/opioid-task-force-progress-report.pdf.

[14] U.S. Dep't of Just., Drug Enforcement Admin., Preventing Diversion, https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-13)%20Preventing%20Diversion.pdf.

[15] *Id*.

[16] Deposition of Dennis Troughton ("Troughton Dep.") at 100:16-23.

- Patient demands immediate attention or behaves suspiciously;
- Patient recites textbook symptoms or gives vague medical history;
- Patient exaggerates medical condition;
- Patient wants a prescription filled 15 minutes before the pharmacy closes;
- Patient is unwilling to have pharmacist call their doctor;
- Patient claims they failed to pack medication, lost it, or that it was stolen;
- Patient deceives doctors or seeks alternate doctors while normal doctor is out of the office;
- Patient solicits Medicaid recipients to use Medicaid cards as payment method;
- Patient offers to buy other patient's pills;
- Patient alters prescriptions;
- Patient is unwilling to give personal information such as phone number or address;
- Patient claims that prescriber is on vacation and they need a refill;
- Patients requesting a refill too early;
- Patient offers to pay cash when they have prescription insurance;
- Patient travels long distances to their pharmacy or prescriber;
- Patient obtains multiple prescriptions from different prescribers;
- Patients travel to multiple pharmacies to fill prescriptions;
- Patient presents a prescription written on a stolen prescription pad.
- Fictitious records
- Wounds inflicted to self, family members, and pets
- Requests specific medication due to allergies
- Vacationing in area, no local address
- Requests pain medications for a pet

Red flags are guidelines to help make informed decisions, they are not the law.[17] In fact, there are no Federal Laws or Georgia Laws that identify specific computations for red flags or explicitly stating what a pharmacist must do after identifying one. Importantly, red flags are adapted to a specific region based upon the pharmacist's expertise of the community they serve.

b. Resolving Red Flags

The "red flags" identified above can be managed at the pharmacy level. The pharmacists use professional judgment when assessing suspicious behavior and/or fraudulent prescriptions.

There are no governing national or state laws or practices telling pharmacists what, if anything, they must document when exercising their professional responsibility to evaluate and dispense a prescription.[18] In fact, while Georgia law requires documentation in certain instances, such as documenting refills on an original prescription when a refill is authorized by a practitioner,[19] it is

[17] *See* Troughton Dep. at 100:16-23.
[18] Ga. Code Ann., §§ 26-4-1-119; Deposition of Kimberly Kaptain ("Kaptain Dep.") at 80:6-18.
[19] Ga. Code Ann. § 26-4-80(e).

silent as to documentation requirements regarding red flags and refusal to fill controlled substance prescriptions.

Pharmacists utilize their professional judgment to decide whether they need to document that communication with the prescriber. Depending on the situation, a pharmacist may place a note on the hardcopy of the prescription, a note in the computer, or fill the prescription without any additional documentation. Documentation stating that all red flags have been resolved is not necessary because the fact that the opioid prescription is filled, in and of itself, confirms that any red flags were cleared by the pharmacist.

In my practice, none of the companies I worked for provided standards advising pharmacists what to document and that is consistent with the standard of care in Georgia. This is also true for the hundreds of pharmacists I have consulted with across the country while conducting my research, attending conferences, and maintaining knowledge sufficient to teach future pharmacists. The decision to annotate or document the identification and resolution of red flags was up to my professional judgment.

In most cases, the pharmacist will use their professional judgment and share the information as a professional courtesy to a pharmacist at another store down the road. Of note, to put a note in the electronic system, a patient must have a patient profile with the pharmacy. Therefore, in situations where a pharmacist refuses to fill the prescription of a patient that does not have a patient profile with the pharmacy (i.e. a new patient to the pharmacy), there was, and still is, no way to document that the red flag went unresolved and the prescription was not filled.

c. Prescription Drug Monitoring Program (PDMP)

PDMP is an electronic database that tracks controlled substance prescriptions for patients. The timeline for the implementation and use of the Georgia PDMP is below:

- 2011 – PDMP signed into law[20]
- 2013 – June 14: Georgia's PDMP went live[21]
- 2016 – July 1: Georgia's PDMP regulations were updated: (1) All Dispensers are mandated to submit information into Georgia's PDMP for dispensed Schedule II, III, IV, and V controlled substance prescriptions within 24 hours (previously 10 days) after the substance is dispensed; (2) all prescribers are mandated under certain conditions, to check the PDMP prior to prescribing Schedule II, III, IV, or V substances; (3) Georgia's PDMP will be housed with Georgia's Dept. of Public Health (DPH); and (4)

[20] Leitman, Rachel, *Georgia's Fight Against Prescription Drug Abuse*, Georgia Senate Research Office, (July 2013) https://www.senate.ga.gov/sro/Documents/AtIssue/atissue_July13.pdf.
[21] *Id*.

DPH is mandated to test the PDMP randomly "to determine if it is accessible and operational 99.5 percent of the time;" among other changes.[22]

- 2017 – July 1: All dispensers required to enter prescription information for Schedule II, III, IV, V controlled substances within 24 hours.[23]
- 2018 – Jan. 1: All prescribers required to register in the PDMP by Jan. 1, 2018.[24]
- 2018 – July 1: Prescribers initially prescribing a Schedule II opioid or any benzodiazepine shall seek and review a patient's PDMP information, then at least once every 90 days thereafter.[25]
- 2022 – The Georgia Board of Health announces the implementation of Bamboo Health's PMP Gateway service that will allow pharmacy dispensing software to integrate directly with the Georgia PDMP. This technology development by the State of Georgia will allow "eliminate the need for providers to navigate to the PDMP website, log in, and enter their patient's information." This capability was not activated by the State until 2023.[26]

Although PDMPs have the potential to provide pharmacies with timely information about prescribing and patient behaviors, accessing this information in a community pharmacy was quite challenging and is still challenging in some places. The Georgia PDMP could not be integrated into pharmacy dispensing software until 2023. This means that until 2023, pharmacists in Georgia, not just those at Publix, needed to use a separate login and password to access the PDMP database. They had to toggle between two systems and often re-login each time in order to use PDMP while filling prescriptions. My review of Mr. Catizone's General Report on page 70 indicates that Mr. Catizone may be of the opinion that Publix was responsible for the difficulty in accessing the Georgia PDMP, but that is not the case based on the information above.

Further, I confirmed during my interview with Leigh Anne Jacobson at Publix that the Georgia PDMP (like other PDMPs in the industry) only permits querying by patient. It is not a database that can be used to query for or monitor prescriber activity. There is no requirement under Georgia law for pharmacists to check the PDMP prior to dispensing a controlled substance prescription.[27]

ii. Counseling on Controlled Substances Prescriptions

Pharmacists will exercise their due diligence and, if the suspicious circumstances are resolved, will dispense the prescription. If the pharmacist does not resolve the suspicion, they will not fill

[22] EMSTAR Research, Inc., An Assessment of Prescription Drug Abuse, Underage Drinking, and Georgia's Prescription Drug Monitoring Program (July 2017), https://stoprxabuseinga.org/wp-content/uploads/2018/08/PDMP-Assessment-2017-Report-updated-09-25-2017-1.pdf.

[23] Ga. Dep't of Pub. Health, Prescription Drug Monitoring Program, dph.georgia.gov/pdmp.

[24] *Id*.

[25] *Id*.

[26] Ga. Dep't of Pub. Health, PDMP Integration,dph.georgia.gov/pdmp/pdmp-integration.

[27] Ga. Dep't of Pub. Health, Prescription Drug Monitoring Program, dph.georgia.gov/pdmp.

the prescription. To evaluate the prescription's legitimacy, a pharmacist uses many tools at their disposal such as their knowledge of the medicine, knowledge of the patient, knowledge of the prescriber, and knowledge of the community. Pharmacists follow the pharmacists' patient care process when evaluating the patient, which includes complying with state and federal law. The evaluation of each prescription fill is individual for each patient and based on the specific facts.

At the time of dispensing, every patient has the opportunity to receive counseling on their medication. When counseling a patient, a pharmacist uses their professional judgment to provide appropriate information based on the relevant circumstances. For opioids, the counseling typically includes information regarding proper administration, how to properly store opioids, how to properly dispose of opioids, and relevant safety concerns. Risks discussed are individualized to the patient and may include the following: constipation, dependency, dizziness, drowsiness/sedation, drug interactions (if one exists), falling, overdose, respiratory depression (having trouble breathing), tolerance (needing more medication to help manage pain), that the patient may experience nausea or vomiting, and that the patient may experience confusion.

iii. Rejected or Refused Controlled Substance Prescriptions

When a pharmacist refuses to fill a controlled substance prescription (or any prescription for that matter) there is not a state or federal law that tells the pharmacist what to do with the prescription. The pharmacist may keep the prescription or give the prescription back to the patient. In certain situations, the pharmacy may call the police and involve law enforcement. Any of these decisions are at the discretion of the pharmacist. I have worked at three different community pharmacy organizations and depending on the situation I have done all three—kept the prescription, gave it back to the patient, and/or contacted law enforcement. A pharmacist's decision, in the exercise of their discretion, not to fill a prescription does not make the prescription illegitimate in fact.

iv. Corporate Oversight

From 2006-2019, the tools available to chain pharmacies to monitor their individual store locations and pharmacists evolved as technology developed and as the enforcement guidance and actions from DEA and state Boards of Pharmacy developed. There was no uniform or generally accepted practice at the beginning of this period in 2006, nor at the end, regarding the type of oversight or tools that pharmacy owners should use to monitor the dispensing of opioids at their pharmacies. Generally, I am aware that some pharmacies monitored stores for overall opioid threshold or maximum quantities of opioids that could be ordered or dispensed, for theft or losses (including monitoring the quantity sold vs. the quantity in inventory to see if there are any discrepancies), for increased sales in higher strength opioids, and for the percent of opioids or Schedule II drugs dispensed as compared to the overall prescription count. Some pharmacies conducted this analysis at the corporate level, and only involved individual pharmacy employees where further investigation was warranted. Overall, the primary requirement of pharmacy owners or leadership was to not hinder the pharmacist's exercise of their professional judgment, including the exercise of discretion in determining when and whether to fill a particular

prescription. That determination is the core of what is referred to as the "practice of pharmacy" which can only be performed by a licensed individual pharmacist. Corporations and pharmacies cannot become licensed to engage in the practice of pharmacy and likewise cannot engage in the practice of pharmacy.

v. Changes and Limitations in Pharmacy Technology

Another item that changed for the profession since I graduated is technology. When I first graduated, computer software from one pharmacy did not "talk" to another. Pharmacists in one store within a chain or network of pharmacies could not see or look up or have access to data from another store in the chain. This required pharmacists to talk to each other on the phone to communicate between locations. Within a single location, pharmacists across different shifts learned to leave notes and have shift ending/beginning meetings to transition information from pharmacist to pharmacist.

Further, the electronic or computer systems used by pharmacists in the 1990s and early 2000s were simple and often DOS-based software systems with dot-matrix printers. These systems had little to no ability to document patient notes. If documentation occurred it typically happened as a handwritten note on the hard copy prescription. If a pharmacist or an auditor had a question about a particular prescription, they had to "pull the hard copy" from the pharmacy's files. Prescription records were typically kept in file cabinets in the pharmacies in a secure place in the store. It was not until the late 2010s that technology platforms in pharmacies became Windows-based with expanding capabilities.

An example of a Windows-based platform is EnterpriseRx—this is the third party system Publix began using in Cobb County in approximately 2010.[28] The EnterpriseRx workflow is generally similar to the other Windows-based platforms, including Pioneer, QS1, EPRN, and Rx30. The technology allowed pharmacies to scan prescriptions into the software so they could be electronically filed. If a pharmacist had a question about a particular prescription, they could now "pull up the electronic copy" on a computer screen instead of going through filing cabinets to find the "hard (printed) copy." Documentation in the Windows-based platform also occurred. The pharmacist tied their documentation to the scanned prescription just as they had tied it to a hard copy prescription. The note stayed with the prescription and if a pharmacist had a question about a particular prescription, they would need to pull the scanned prescription to see what the note said.

The Windows operating systems were a major (and welcomed) change for the profession; however, they still have their limitations even today. The systems lack the greater functionality associated with electronic medical records. And while there are often ways to document in the system, different fields of information may "stay with" a patient, a prescription, or a prescriber, and others do not. Also, many fields of information have limitations on how many characters can

[28] Deposition of Chris Hewell ("Hewell Dep."), Oct. 7, 2022, at 206:10-18.

be used, constraining the space. A pharmacist can document in EnterpriseRx at multiple points within the workflow of dispensing a prescription.

The typical clinical workflow supported by such a system is as follows:

- Pharmacy receives the prescription
- Data entry of the prescription
- Drug Utilization Review (DUR) occurs
- Pre-verification 1 – May be done by a technician or a pharmacist
- Dispensing of the prescription with scan of the hard copy into the system
- Pre-verification 2 – Must be done by a pharmacist in most states including GA
- Prescription is ready for pick up and in the holding area
- Release to patient (payment and sale transaction typically occur in a separate software system)

You can document a prescription note during any step of the process listed above. When a note is documented in any of the above steps, that note is tied to the prescription. You can also have notes that are tied to a prescriber or tied to a patient. The notes appear in separate fields in the system depending on where you place your documentation. There is not one place in the software system to place all your documentation. It must be tied to a patient, a prescriber or a prescription and these do not exist on one screen for the pharmacist to see. To inform a pharmacist that a note exists for a particular patient, these software systems will typically alert the pharmacist by flashing something on the screen or using a different coloring scheme to signify a note is present.

In addition to prescription, prescriber and patient notes, Windows-based systems also allow for notes to be transactional in nature. For example, if a pharmacist decides to counsel a patient at point of sale, then this documentation stays with that transaction, and it not tied to a patient or a prescription. The pharmacy dispensing software used in community pharmacies were not built to be a robust documentation system for electronic medical records. The primary purpose of these Windows-based systems are to manage process flow associated with dispensing prescriptions, not to create a transcript of the steps a pharmacist takes to evaluate a prescription or exercise corresponding responsibility.

4. Opinions Regarding Publix's Conduct and Activities

In developing my opinions in this case, I reviewed various documents, including documents from Publix, and the Georgia Drugs and Narcotics Agency, as well as Rules & Regulations related to Georgia pharmacy practices, and deposition transcripts, including the deposition exhibits, of Publix pharmacists and GDNA personnel. I have also spoken with Publix Pharmacy Operations Manager, Lindsay Burckhalter, and Pharmacy Supervisor, Leigh Anne Jacobson (both of whom have been Publix pharmacy employees in Georgia since 2008), regarding Publix's pharmacy practices. Each of these materials and discussions have informed my opinions in this case.

Based on my review of the materials in this case, my discussions with Lindsay Burckhalter and Leigh Anne Jacobson, and my professional experience, it is my opinion that Publix has adhered to the standard of care and that its practices aligned with the typical industry custom and practice of community pharmacists regarding the dispensing of opioids as that has evolved from 2006-2019.

Publix followed industry standards for pharmacy inventory, technology, and training, and they maintained a healthy work environment for pharmacists to exercise their best judgment and appropriately dispense controlled substances in their pharmacies. The policies and procedures ensured that patient safety was considered, and pharmacy practice laws were followed.

Based on my review of the pharmacy operation policies and procedures, Publix pharmacists' abilities to carry out their duties aligned with pharmacy practice laws in the state of Georgia and were consistent with federal rules and regulations.

Publix provided their pharmacists with data and tools necessary to fulfill the pharmacist duties, including but not limited to, access to PDMP, access to ACPE continuing education, and training resources on providing their pharmacists with encouragement to exercise their independent professional judgment.

A. Publix Hires and Trains Pharmacists in Accordance with the Industry Standard of Care and Custom and Practice

i. Publix New Hire Training and Internship Program

Publix's policies and procedures for hiring and onboarding of pharmacists are consistent with the standard of care.

Prior to hire, Publix verifies pharmacists are licensed professionals. By hiring licensed professionals who have passed national and state level board exams, Publix is ensuring that they are hiring highly-trained individuals that can exercise their professional judgment to make informed patient decisions for medication dispensing.

When Publix hires a new pharmacist, the company requires a two-week training, which consists of four 8-hour days the first week and four 10-hour days the second week.[29] This training mandates the new hire work alongside a current Publix pharmacist. I learned from my conversation with Lindsay Burckhalter that this new hire one-on-one initial training program has been part of the company for at least the past 15 years. During this initial training, the new hire completes any computer-based training specific to the company's policy and procedures. The Training Facilitator Materials indicate that new hires were also required to undergo training on

[29] *See, e.g.*, Hewell Dep., Oct. 7, 2022, at Exs. 26 Pharmacist I / New Hire Graduate Intern Training Student Workbook (April 29, 2015), at 1, 28 Pharmacist I / New Hire Graduate Intern Training Student Workbook (April 26, 2019), at 1.

regulatory references available on the Publix intranet including State Boards of Pharmacy websites, DEA Diversion Control Program website and the Georgia Drugs and Narcotics agency website.[30] The new hire also works side by side with the pharmacist and gets immersed into the company's customer service focus. This one-on-one training builds in an automatic mentorship to the company so the new hire will feel embedded in its culture. In my experience this one-on-one onboarding/training program is compliant with the industry standard. When I was new to my independent pharmacy and the regional chain pharmacy, we only received a 40-hour onboarding/training period.

In addition, Publix hires pharmacists who have been part of their pharmacy intern program. This is typical of any pharmacy employer. The internship program is viewed as a long interview process. It gives the company substantial information to evaluate a pharmacist candidate and to avoid hiring individuals who are not up to Publix's standards. If a company decides to hire an existing intern, they have been vetted to understand culture, patient care, and policies and procedures for the company. During my career I was promoted from student intern to graduate intern to pharmacist with a national pharmacy chain. When I was hired as a pharmacist for the company, I received less than 40 hours of onboarding/training when I became a licensed pharmacist. When I reviewed Publix's procedures for hiring a new graduate intern,[31] and discussed the new hire training process with Lindsay Burckhalter, I was surprised to learn that their interns go through almost double that amount of training hours upon hire. This demonstrates that Publix is a company dedicated to ensuring they hire and train the best pharmacists.

ii. Resources Provided to Publix Pharmacists

Publix provides references and resources that support its pharmacists, which are updated over time as appropriate. Publix pharmacists may access Drug Store News and Pharmacist's Letter, which are two reliable and reputable training materials. On the company Intranet, pharmacists may access computer-based trainings, a morphine milligram equivalent (MME) calculator, the naloxone standing order guide, and weekly memos and other correspondence from pharmacy leadership to keep Publix pharmacists informed of industry developments, including those related to controlled substances and opioids.[32] Publix pharmacies and pharmacists could access the store company email from the Intranet and Leigh Anne Jacobson confirmed that Weekly Memos and other updates from pharmacy management would usually be printed and posted for all pharmacy workers to review.[33]

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[30] PUBLIX-MDLT8-00060684-782, at 755 (2011 Pharmacist I Training Facilitator Guide at 69).

[31] *Id.*

[32] PUBLIX-MDLT8-00073489 (2008 Ottolino email regarding change in controlled substance receiving in light of theft); PUBLIX-MDLT8-00098454-56 (2010 Weekly Memo updating pharmacists regarding DEA guidance on electronic prescribing of controlled substances); PUBLIX-MDLT8-00098530-33 (2011 Weekly Memo informing pharmacists of Georgia PDMP legislation); PUBLIX-MDLT8-00087991-93 (2011 Email from Mike King to Atlanta Pharmacies forwarding information from the Georgia BOP regarding security paper requirements for controlled substances); PUBLIX-MDLT8-00098583-88 (2012 Weekly Memo regarding DEA Pharmacist's Manual on Corresponding Responsibility).

[33] Interview of Leigh Anne Jacobson.

Contrary to Dr. Lembke's assertions, the training that Publix provided and made available to its pharmacists was appropriate, including ACPE CE materials. I disagree with Dr. Lembke's testimony stating that pharmacists should be conducting independent reviews of the CE-type materials from the FDA, DEA, NACP and NACDS. It is well accepted by pharmacists that these organizations have reliable and reputable information that pertains to their practice. During training and education, a pharmacist learns how to evaluate when information is reliable and reputable. Pharmacists rely on ACPE CE standards to guide requirements. Companies belong to national associations such as NACDS and one of the member benefits is providing CE requirements, which is part of the membership dues. This aligns with a pharmacist belonging to a national pharmacy association such as APhA. The national associations are held to the same standards of ACPE CE requirements when they disseminate information to their members. I have attended and claimed CE credit for numerous courses that are sponsored by national associations. I have also attended and claimed CE credit for numerous courses sponsored by a manufacturer of a medication. Industry sponsored CE events underwent a massive shift in the early 2000s. This shift required manufacturers to abide by the ACPE CE requirements and to have an expert in the subject speak rather than an employee of the manufacturer.

Further, at the time of hire, Publix provides the pharmacists with the Publix Pharmacy R&P Guide to review. The Publix R&P Guide, Chapter 8: Regulations and Associated Publix Policies details what company policies pharmacists must follow. The R&P Guide included information about opioid and controlled substance policies and procedures, which aligned with the changing practice norms.

Publix's pharmacy team also brought such updates and information about pharmacy trends, including those related to controlled substances, to the attention of its dispensing pharmacists through regular email communications[34] and regular store visits by pharmacy supervisors.[35] The pharmacy supervisors would visit their stores every 4-6 weeks. These visits ensured that any new or updated policies were being implemented in the pharmacies. Publix pharmacy team leadership encouraged supervisors to discuss updated policies with their teams, and invited questions and feedback as new information was rolled out.[36]

Based on the information available at the time, Publix was timely with their opioid updates in their company's policy and procedure manual. They were also timely providing their pharmacists with training materials for opioid updates. The company provided an opioid refresher shortly after the CDC guidelines for opioids were published in 2016. They updated the Intranet and provided an MME calculator for pharmacists to use once this data was published in the CDC guidance document. They also released computer-based training specific to opioids after the

[34] *See, e.g.*, Deposition of Leigh Anne Jacobson ("Jacobson Dep."), Ex. 28 (June 2018 email discussing and attaching "CS Threshold Training for Pharmacy Supervisors", PUBLIX-MDLT8-00071354-56); Deposition of Kathy Leonard ("Leonard Dep."), Ex. 3 (May 2019 email from Kathy Leonard to Dennis Santaniello PUBLIX-MDLT8-00132823-63).

[35] *See, e.g.*, Jacobson Dep. at 75:21-76:16; Deposition of Dain Rusk ("Rusk Dep.") at 18:7-19:13; 68:22-70:5.

[36] *See* Jacobson Dep., Ex. 28 (June 2018 email discussing and attaching "CS Threshold Training for Pharmacy Supervisors", PUBLIX-MDLT8-00071354-56).

CDC guidelines were released. All of this reinforces and supports that Publix provided ongoing support to supplement their pharmacists' education, training, knowledge and experience so they could use this information while exercising their professional judgement as a pharmacist.

Further, the pharmacy supervisors and pharmacy team leaders at Publix are all pharmacists—this is not typical of the industry. Having supervisors who are pharmacists overseeing pharmacy operations and policies and procedures acts as an internal quality improvement process for the entire team. This culture is unusual in community pharmacy practice. When a pharmacy supervisor visits a store, you can get an opinion of another pharmacist about how your store business is being run. Through these eyes, clinical care is considered, and it is not just someone interested in the profit and loss of the business.

iii. Publix Enforced Policies Related to Fraud and Theft

Chapter 8 in the Publix R&P Guide outlines policies related to fraud, substance abuse, and identifying invalid controlled substance prescriptions. It clearly outlines disciplinary actions if an employee is caught abusing or stealing from the company. The materials I reviewed demonstrated that Publix enforced this policy and procedure when an employee was caught stealing.[37] Publix has adequate policies and procedures in place to ensure diversion does not occur at the pharmacy level.

B. Publix's Controlled Substance Policies and Practices Aligned with the Usual Custom and Practice of Community Pharmacies As They Evolved Between 2006-2019

i. A Pharmacy's Support of a Pharmacist Should Not Interfere with a Pharmacist's Duty to Exercise Their Independent Judgment

As discussed throughout, pharmacists learn how to practice pharmacy during school, their internships, and through working as a pharmacist. A company's policies should not interfere with a pharmacist's ability to perform their duties. Publix pharmacists were always supported by leadership when the pharmacist exercised their clinical and professional judgment to refuse to dispense an opioid [or any] prescription.[38] This demonstrates appropriate organizational support for the exercise of corresponding responsibility. Internal communications between Leigh Anne Jacobson and Publix Customer Care is an example where a pharmacist refused to fill a prescription based on professional judgment.[39] In this case, the patient even involved the physician, and the pharmacist held her ground and refused to dispense a controlled substance due to her judgment. The pharmacist's decision was supported by the company.

ii. Publix Had policies on Forgery and Fraud Consistent With the Typical Community Pharmacy in the Early 2000s

[37] *See, e.g.*, Ottolino Dep. at 192:23-194:17.
[38] *See, e.g.*, Ottolino Dep., Ex. 1 (2011 Memo, PUBLIX-MDLT8-00118914-15).
[39] Jacobson Dep., Ex. 27 (July 22, 2020 customer complaint, PUBLIX-MDLT8-00080521-22).

Publix has long expected its pharmacists to guard against and report fraud and abuse identified in the course of dispensing medications.[40] The company's policies reflect that suspected invalid controlled substance prescriptions were likewise reported up to supervising pharmacists and leadership.[41] According to the 2021 Publix Pharmacy R&P Guide Regulations and Associated Publix Practices 8-65, it is the responsibility of the pharmacist on duty to share this information with their pharmacy supervisor. The testimony of Publix's pharmacists demonstrates that relevant information about suspicious circumstances is distributed through the management chain of command.

iii. Publix Supported Pharmacists in Red Flag Identification and Resolution

Based on the evidence I've reviewed, Publix pharmacists identified and resolved "red flags" related to controlled substance prescriptions, and Publix provided appropriate support for pharmacists to exercise their best professional judgment in evaluating those factors.

a. Before 2012, Pharmacists Were Aware of Circumstances or Facts That Indicate a Prescription May Not Be for a Legitimate Purpose

After reviewing Publix policies and procedures for dispensing of controlled substances in the time period 2006-2021, their policies align with standard pharmacy practice and are consistent with applicable Georgia law. Publix had appropriate measures in place to allow pharmacists to identify and evaluate "red flags." The testimony provided by the Publix employees demonstrates that Publix was following industry standard for dispensing controlled substances.

I disagree with Dr. Lembke's and Catizone's conclusion that Publix's R&P guide did not address any red flags prior to 2012. For example, altered or forged prescriptions are commonly considered a "red flag." Prior to 2012, the R&P Guide reflected priorities and policies for suspected fraud, including prescription forging or altering,[42] as well as deterring methamphetamine substance abuse.[43] These policies are aligned with industry standards and the focus of anti-diversion efforts to combat forgeries and fraud, which were viewed as the primary driver of illegitimate prescriptions during this period. Based on my experience and exposure to numerous pharmacists, training, and my review of industry and academic materials, it would have been unusual for a company to have a specific "red flag" policy from 2006-2012.

b. Publix's Introduction of "Suspicious Circumstances" Guidance in 2012 Was Appropriate and Consistent with the Industry Standard of Care

[40] *See, e.g.*, 2007 R&P Guide at 8-21 (PUBLIX-MDLT8-00025512-44, at 32) (requiring employees to report suspected instances of healthcare fraud and abuse to either pharmacy supervisors, corporate counsel, or through an ethics hotline).

[41] 2012 R&P Guide at 8-38 (PUBLIX-MDLT8-00027405-449, at 42) (discussing handling and reporting of suspected invalid controlled substance prescriptions); 2021 R&P Guide at 8-65 (PUBLIX-MDLT8-00056044-142, at 108) (discussing notifying the pharmacist on duty of a suspicious or fraudulent controlled substance prescription).

[42] 2007 R&P Guide Sec. 8-17 (PUBLIX-MDLT8-00025512-44, at 28).

[43] 2007 R&P Guide Sec. 8-10 (PUBLIX-MDLT8-00025512-44, at 21).

As the industry changed, and the methods and types of diversion evolved, so did regulators, the industry, and Publix. In May 2011, Publix shared information with its pharmacy team regarding trends in prescription opioid abuse and recent DEA guidance on that topic.[44] In 2012, Publix's updated R&P Guide included examples of specific suspicious circumstances related to opioid medications to further supplement pharmacists' knowledge for us in the evaluation of potentially invalid prescriptions.[45] There is also guidance about handling and reporting fraudulent prescriptions, with citations to the corresponding federal regulations. Publix required all pharmacists to review the Guide and affirm that they had read and understood it.[46] Additionally, Publix's supervisors discussed the concepts in the Guide with pharmacists when visiting individual stores.[47]

I disagree with Dr. Lembke's opinion that the examples provided in Publix's 2012 R&P Guide titled "Identifying Invalid Controlled Substance Prescriptions" were untimely or inconsistent with the standard of care. During this time, there were increasing updates from industry organizations regarding the opioid epidemic and specifically highlighting potential warning signs of illegitimate prescriptions. Specifically, the DEA through its Pharmacist's Manual, as well as the NABP and some state boards of pharmacy, issued public statements during this same period. The timing of Publix's R&P Guide updates on this topic are relatively consistent the industry. Publix's guidance is also consistent with the timing of the GDNA implementing a Supplemental Form and guidance regarding "red flags."[48] Publix continuously required its pharmacists to comply with federal and state laws governing the practice of pharmacy.[49]

The materials I reviewed show that Publix continued to stay up to date with current industry trends and had a system in place to inform employees of those trends. In 2013, Publix shared with the Pharmacy team information received from DEA personnel just a week earlier regarding recent trends in pill mills, problematic prescribing physicians and "bad pharmacist decisions."[50] This was timely information. The 2013 email of Paul Hines incorporates DEA manual references with employees asking them to be further shared so that this information can be incorporated into their evaluation and decision-making processes.[51] From a pharmacist perspective, Publix took action, through this email, to equip the right personnel with emerging trend information. In fact, it was not until 2015 when organizations such as the American Public Health Association developed policy language for pill mills.[52] In addition, Publix reminded pharmacists to use the

[44] *See, e.g.*, Ottolino Dep., Ex. 1 (2011 Memo, PUBLIX-MDLT8-00118914-15).
[45] 2012 R&P Guide 8-34 (PUBLIX-MDLT8-00027405-449, at 38).
[46] Publix Controlled Substances Policy (2018) (PUBLIX-MDLT8-00058608-22).
[47] Deposition of Michael King ("King Dep.") at 132-136; Interview with Leigh Anne Jacobson.
[48] Troughton Dep., Ex. 9 (GDNA Retail Pharmacy Permit Inspection Form, GDNA00006179-81).
[49] *See*, *e.g.*, 2018 R&P Guide (PUBLIX-MDLT8-00023640-708, at 686-87).
[50] Ottolino Dep., Ex. 16 (March 2013 email regarding "Recent DEA Interaction", PUBLIX-MDLT8-00066086-88).
[51] *Id.*
[52] American Public Health Association, Prevention and Intervention Strategies to Decrease Misuse of Prescription Pain Medication (Nov. 3, 2015), https://www.apha.org/policies-and-advocacy/public-health-policy-statements/policy-database/2015/12/08/15/11/prevention-and-intervention-strategies-to-decrease-misuse-of-prescription-pain-medication.

naloxone standing order when they felt it was warranted. Publix also had an Anti-Diversion Processes policy outlining all the ways in which Loss Prevention, Pharmacy Operation Processes, Pharmacy Procurement Processes and Pharmacy Warehouse Processes helped prevent diversion of controlled substances.[53]

The materials I reviewed also show that Publix pharmacists learned about identifying and evaluating red flags from visits and interactions with GDNA agents. For example, GDNA Director Dennis Troughton testified about GDNA inspections and how a GDNA agent will discuss red flags with pharmacists during these inspections.[54]

In my view, these considerations were relevant and appropriate guidance for its pharmacists because it was consistent with the standard of care in the industry at the time. Further, the guidance did not attempt to provide an exhaustive list, but rather provide information for pharmacists to consider when exercising their requisite professional judgment. It would be impossible for Publix to provide a rigid, fixed list of red flags to adhere to since every patient and every prescription needs to be treated individually and at the professional judgment of the pharmacist.

iv. Publix Pharmacists' Sharing of Information Was Appropriate

Based on my analysis, Publix pharmacists shared information about potential fraud, forgery, suspicious circumstances, and red flag issues through an informal but effective communication network. For example, Publix pharmacists shared information about falsified prescriptions via email or phone.[55]

Prior to PDMP, communications between different pharmacy chains regarding suspicious prescriptions, patients, and prescribers occurred by phone. This was the most efficient way for pharmacists to inform colleagues at other pharmacists of suspicious prescriptions, patients, or prescribers, especially given technology limitations. In addition to communicating with other pharmacies by phone, pharmacists would also communicate internally. These internal communications include leaving post it notes for their partners on the next shift, placing documentation in a patient basket for a specific prescription or having a drawer of notes to communicate extensive patient information that would not fit into the dispensing software due to character limits. Publix's use of email for this purpose is consistent with my experience.[56] Email and phone calls can get the word out immediately, as opposed to Georgia's PDMP, which, beginning July 2017, only required pharmacies to input dispensing information for controlled substances every 24 hours. Even after the implementation of the PDMP, all the aforementioned

[53] Controlled Substance Anti-Diversion Processes, April 5, 2014 (PUBLIX-MDLT8-00140719-50).

[54] Troughton Dep. at 96:5-101:2.

[55] Deposition of Joseph Wells ("Wells Dep."), Ex. 6 (2018 prescriber alert email, PUBLIX-MDLT8-00086381); Deposition of Lindsay Burckhalter ("Burckhalter Dep."), Ex. 6 (Emails between Publix stores regarding forged prescriptions, date range from Nov. 2015-Jan. 2021, PUBLIX-MDLT8-00082267-34).

[56] Burckhalter Dep., Ex. 6 (Emails between Publix stores regarding forged prescriptions, date range from Nov. 2015-Jan. 2021, PUBLIX-MDLT8-00082267-34).

activities still occur. The PDMP supplements information available to us; it is not a substitute for communications amongst pharmacists.

As discussed above, the decision of whether or not to document the evaluation of a "red flag" is left to a pharmacist's professional judgment. In my practice of pharmacy, none of the companies I worked for provided standards advising pharmacists what to document. Nor did Publix require its pharmacists to document the resolution or evaluation of red flags.[57] As GDNA Director Troughton testified, there is no policy, guidance, standard, or rule about how a pharmacist should document any perceived red flags.[58] Pharmacists are health care professionals. The public trusts pharmacists to make sound clinical decisions related to medications and pharmacy practice just as pharmacists trust physicians to make sound clinical decisions about diagnosis and medical practice. It is not standard health care practice to document the decision making process.

v. Publix Pharmacists Appropriately Used Georgia's Prescription Drug Monitoring Program

Publix incorporated Georgia's prescription drug monitoring program (PDMP) checks into their workflow and had adequate policies and procedures advising pharmacies when to consult the PDMP. Publix's R&P Guide provides guidance on how to identify invalid controlled substance prescriptions with reference to the PDMP. This was first incorporated in the 2012 version of the R&P Guide, shortly after a PDMP was passed into Georgia law but years before the system was fully operational. The R&P Guide discussion on use of the PDMP database evolved in subsequent versions of the guide. For example, the 2019 Pharmacy R&P Guide advises that the PDMP should be checked to identify and guard against invalid practitioner-patient relationships and to acquire relevant information to determine validity of a prescription.[59] However, the PDMP data is only a useful tool if accurate and robust data has been supplied. As discussed earlier, it was not until July 1, 2017 that Georgia required dispensers to enter controlled substance dispensing information within 24 hours of dispensing, and prescribers were not required to register in the PDMP until January 1, 2018.[60] Thus, the usefulness of the PDMP was limited during this time.

Additionally, as discussed throughout, due to technological limitations, the Georgia PDMP could not be integrated into pharmacy dispensing software workflow, including the Publix dispensing software workflow, until 2023.[61] This lack of integration was typical of any new pharmacy software system. Integration is rare. In fact, there is software called OutcomesMTM[62] for medication management for Medicare Part D patients that has been available since 2008. To this day, that software is still not integrated into every pharmacy dispensing software system, yet it is used every day when pharmacists perform medication reviews for patients over age 65 with Medicare Part D insurance coverage. Pharmacists must toggle between their pharmacy

[57] Deposition of Jillanne Smith ("Smith Dep.") at 374:24-375:14.
[58] Troughton Dep. at 100:10-101:2.
[59] Wells Dep., Ex. 3 (2019 R&P Guide, PUBLIX-MDLT8-00012235).
[60] Ga. Dep't of Pub. Health, Prescription Drug Monitoring Program, dph.georgia.gov/pdmp.
[61] *See* Wells Dep. at 231:19-232:21.
[62] OutcomesMTM, https://secure.outcomesmtm.com/.

dispensing software and this online platform to manage their patients who require services for OutcomesMTM. The PDMP tool followed the same concept. Until PDMP could be integrated into dispensing software in 2023, the pharmacist was required to toggle between their pharmacy dispensing software and the web-based platform where the PDMP is located to take care of their patients.

Based on my review, and consistent with the standard of care in Georgia, Publix relied on the professional judgment of its pharmacists to determine when the use of PDMP was necessary. Publix pharmacists would make this determination based on their judgment of the individual circumstances for each individual prescription. Georgia law does not require the PDMP to be checked with every prescription fill and a pharmacist will not check the PDMP with every opioid prescription dispensed. For example, if the patient is a regular at my store and I have no reason to suspect the prescription is illegitimate, I will not check the PDMP, as I have no reason.

C. Publix Pharmacies Used Dispensing Technology that Aligned with the Usual Custom and Practice of Other Community Pharmacies During the Relevant Time Period

During the time period of 2006-2021, many changes occurred within pharmacy technology. In fact, these are still occurring. Publix and its pharmacists changed with the times with regard to technology. Publix's pharmacy dispensing software was consistent with the standard of care at the times that the various programs were in use, and the software was updated in a timely and appropriate manner.

Publix's Cobb County stores switched their technology platform to a Windows-based application, EnterpriseRx, in approximately 2010.[63] This change in platform allowed for greater capabilities during workflow. The Windows operating systems were a positive change for the profession; however, they continue to evolve and progress today. The systems are not electronic medical records and there is not a standardized approach to documenting patient care in the system. These Windows-based systems are built to be efficient for managing work flow steps associated with prescription dispensing but not for the process of managing the overall health care of a patient. This technology is still evolving in the industry.

An advantage of the Windows-based system is it allows pharmacists to incorporate information from dashboards. Prior systems, such as PDX, did not have the capability to do this. This was the first time in pharmacy practice that pharmacists had dashboards at their disposable at the store level. Prior to this, dashboards (and therefore data) were not housed with the pharmacy dispensing software. Prior technology systems required a multi-step process to run reports to see inventory and fill rate history. New dashboard style capabilities enabled pharmacists to have access to more information to make informed decisions about the populations they were serving and the prescriptions they were filling at their store. For example, Publix's current system highlights the prescription, prescriber or patient note tab in red if there are any notes present in the respective tab.

[63] Hewell Dep., Oct. 7, 2022, at 206:10-18.

Another significant advancement with this change in technology was the ability to see if a prescription for a Publix patient was filled at another Publix location. As previously explained, prior to a Windows-based system, a member of the pharmacy had to call other Publix locations to obtain this information. Technology did not allow this to be part of the workflow. Based on my experience, this limitation preventing pharmacists from seeing data or information relating to prescriptions filled at other stores in the chain was normal in the industry before 2010.

Another evolution in the technology is reflect in Jillanne Smith's deposition testimony and was reiterated in my interview with Leigh Anne Jacobson. Both of those confirmed that Publix's EnterpriseRx system has worked with a program called RelayHealth to verify that DEA numbers entered for controlled substance prescriptions belongs to a prescriber that is authorized to write for controlled substances. The pharmacy dispensing software will notify the pharmacist if the DEA number is not valid or active and Publix pharmacists cannot complete the dispensing workflow or dispense the medication in this instance.[64]

Further, during my interview with Leigh Anne Jacobson, she explained to me that all pharmacists using the EnterpriseRx system can query prescribers to see the prescriber's history at their particular store going back several years if not more. Publix provided the EnterpriseRx system and this capability to its pharmacists, allowing them to analyze possible trends in the prescriber's prescription history if, in there discretion, they wanted to do so.

5. Analysis of Mr. Catizone's Opinions

I have reviewed Mr. Catizone's General and Specific reports and his testimony in this case. I disagree with his opinions regarding Publix's dispensing policies, customs and practices as set forth most concisely in the Conclusion section of his general report and the Summary section of his specific report. As an example, I disagree with his opinions that Publix "failed to provide their pharmacists with the data and tools necessary to fulfill their corresponding responsibility duties" and that Publix used "performance metrics that impeded their pharmacists' efforts to comply with law and regulations and meet standards of care".[65] I reviewed Publix's policies, customs and practices through the Publix documents, deposition testimony, and interviews I conducted of Publix employees and concluded that Publix was operating its pharmacies in line with the usual custom and practices of community pharmacies and in line with the accepted and expected standard of care.

[64] Smith Dep. at 282.
[65] Catizone Track 8 Specific Report, at 46.

A. Mr. Catizone's List of Stagnant, and Non-Discretionary Red Flags Is Inconsistent with the Standards of Pharmacy Practice

I disagree with Mr. Catizone's opinion that his 14 specific computations of "red flags" must have been known to and applied by pharmacists in Georgia since 2006 to comply with the standard of care when dispensing controlled substances. I further disagree that the presence of one of his "red flags" would always indicate that a prescription might be illegitimate or would always require a pharmacist to stop and pause, to scrutinize the prescription in any particular way, to conduct specific due diligence, or to document that process. Lastly, I disagree that the presence of one or more of Mr. Catizone's "red flag" computations triggered an automatic duty in a pharmacist to document the presence of the flag and the pharmacist's efforts to address or clear the flag.

I reviewed Mr. Catizone's reports and the transcript of his deposition in this case. The overarching problem with Mr. Catizone's red flags is that he presents them as very black and white: these computations are flags, always and in all locations, and they should have always triggered the same reaction by pharmacists without regard to the pharmacist's state of knowledge as to and familiarity with, for example, the patient, the prescriber, and local treatment pattern. That is not how pharmacy was or is practiced. "Red flag" is a very broad term and encompasses various tiers or levels of flags or factors that could, under certain circumstances, indicate to a pharmacist that a prescription may not be legitimate. The best way I can explain it is to say that not all "flags" are the same shade of red or are equal, and therefore not all flags require any, or the same level, assessment by a pharmacist. For example, as detailed below, in some communities a patient that drives 25 miles to visit a pharmacy would not be a flag at all. The circumstances of the pharmacies available in the patient's community may make that distance very reasonable and not indicative of a potentially illegitimate prescription to pharmacists within that community. Determining that such a distance is not a flag within that community absent other circumstances is a decision that is left to the professional clinical judgment of the pharmacist. In other communities, driving 25 miles to a pharmacy may raise a very mild flag to a pharmacist that the pharmacist could reasonably clear in accordance with the usual and customary practice of pharmacists by simply asking the patient one or more questions. And still in other communities and circumstances, driving even 10 miles to a pharmacy where a patient passed 15 other equally reputable pharmacies on the way may raise a more prominent flag to a pharmacist to perform further due diligence to determine that the patient is not "pharmacy shopping."

While some of Mr. Catizone's "red flags" may be grounded in broader concepts of red flags that have become generally accepted within the industry over time, the pharmacy standard of care permits pharmacists to exercise their clinical judgment, taking into account the totality of the circumstances, to determine the degree, if at all, to which a prescription presents with a concerning characteristic suggesting that the prescription may not be for a legitimate purpose.

Moreover, any time a pharmacist perceives facts indicating a prescription might not be for a legitimate medical purpose, the pharmacist's training and education would prompt them to have

a conversation with the patient, the prescriber, or otherwise collect information that may be helpful to assessing the legitimacy of the prescription. No single list or set of fixed computations can (or ever should) take the place of a pharmacist applying their clinical judgment to identify possible indications that an opioid prescription is not legitimate.

Mr. Catizone wrongly concludes that his 14 red flag computations were known, or even knowable, and should have been used by every community pharmacist in the period 2006-2021. They were not. Typical community pharmacists were educated and trained on general concepts or categories of red flags such as doctor shopping or pharmacy shopping, but the industry's understanding and statements to pharmacists regarding the categories of such flags evolved and changed over the period of 2006-2021 as I explain more fully below. There was no definitive, accepted list of specific red flag computations or facts that was mandated or even encouraged for use in the industry during that time period, and there remains no such thing today. The precise facts or computations that give a pharmacist knowledge or suspicion that a prescription is not for a legitimate purpose vary depending on the year, the community, and the totality of all the factors presented with a prescription.

1. *An opioid was dispensed to a patient who traveled more than 25 miles to the pharmacy*
2. *An opioid was dispensed to a patient who traveled more than 25 miles to the prescriber.*

The fixed 25-mile limit set by Mr. Catizone is arbitrary. While the circumstance of a patient traveling long distances to obtain a prescription can sometimes indicate suspicious circumstances, in my experience there is no rule, guideline, or common practice that dictates what constitutes a "long" distance. Through my education and teaching and academic pursuits I have not come across a single authoritative source setting forth a specific and rigid mileage count that should be applied by all pharmacists in the United States regardless of location or circumstance, to constitute a "red flag". Nor have I found any source or encountered any community pharmacy establishing 25 miles as a hard and fast rule for triggering a "red flag". Therefore, in my opinion, a patient travelling over 25 miles to a prescriber or a pharmacy could require, in some circumstances, further review or investigation, and in others it would not.

It might very well be the case, particularly in a rural area, that patients regularly travel 25 miles to obtain legitimate prescriptions. In these communities, I would expect that pharmacists would not consider such travel to be indicative of a "red flag" requiring any further activity. Similarly, when patients travel over 25 miles to receive treatment with a specialist, that fact that is often identifiable on the face of the prescription. Consistent with the standard of care in Georgia, GDNA Director Dennis Troughton testified that the GDNA did not have a "set mileage" for identifying patients who travelling a "long" distance or a distance that might suggest doctor or pharmacy shopping.[66]

[66] Troughton Dep. at 97:11-100:8.

3. *Patient was dispensed opioid prescriptions with overlapping days of supply that were written by two or more prescribers*
4. *Patient was dispensed opioid prescriptions with overlapping days of supply at two or more pharmacies*

These computations were not accepted as automatically constituting red flags within the pharmacy industry during the relevant period. As to the first requirement of these two red flags—opioid prescriptions with overlapping days of supply—there are several clinical reasons why this may be happening. For example, a patient's initial dosage may have been insufficient to treat the patient's pain. In this situation, the prescriber would instruct the patient to increase their dosage, resulting in the patient finishing a prescription before the original date of completion. In this situation, a new prescription will be issued at a higher dosage that will inevitably overlap with the original prescription. This type of overlap commonly occurs and is not indicative of a "red flag" that always requires further questioning or action by a pharmacist, especially, for example when it involves a patient who regularly fills prescriptions with and is known to the pharmacist.

As to the prescribers being different for an overlapping prescription, there are numerous situations where the presence of multiple prescribers for overlapping prescriptions would not present any indication of suspicious activity or that the prescription was potential illegitimate.

As written, Mr. Catizone's red flag computation considers a patient obtaining prescriptions from prescribers that work at the same medical practice to be a red flag—it is not. Another example is when a patient originally obtains an initial opioid prescription from a hospital and then a subsequent prescription from their primary care physician. This type of situation can be readily identified from the prescriptions themselves and therefore does not suggest suspicious activity to a typical pharmacist when all the facts and circumstances of the prescription are evaluated upon intake.

Similarly, this type of situation can result in a patient going to two or more pharmacies for overlapping prescriptions—the first pharmacy can be at or near the hospital and the second is closer to the patient's residence. This type of analysis changes by region and varies with the circumstances of each prescription as presented and requires independent evaluation by a pharmacist based on their expertise. Therefore, in my opinion, a prescription presenting with overlapping days of supply by two or more prescribers or at two or more pharmacies does not always present circumstances that require a pharmacist to do more due diligence before dispensing.

5. *Patient was dispensed an opioid, a benzodiazepine, and a muscle relaxer for overlapping days of supply.*
6. *Patient was dispensed an opioid, a benzodiazepine and a muscle relaxer on the same day and all the prescriptions were written by the same prescriber*

I disagree with Mr. Catizone that the "holy trinity" drug combination was known to pharmacists to be a sign of potentially suspicious activity in 2006. As opioid related concerns evolved, it eventually became known among the medical community that the combination of these medications could be an indicator of suspicious activity. However, I disagree with Mr. Catizone that these medications can never be legitimately prescribed in an overlapping period for an overlapping purpose and I am aware of no prohibition imposed by states or the DEA with respect to such prescribing.

Once the medical community realized these medications could indicate suspicious activity, the typical first step in determining whether to fill the prescription(s) was to collect information from the physician to determine if they were intentionally prescribing all three medications at the same time.

The next step would be to assess information from the patient such as discussing potential drug interactions and safety concerns to confirm the patient discussed the medications with their prescriber. In other words, I would use the five steps in the pharmacists' process of care to assess whether I would dispense the opioid. In addition, there are situations where the overlapping of an opioid, muscle relaxer, and benzodiazepine would not trigger any kind of flag or conversation, such as when the patient is well known to the pharmacist or pharmacy and the appropriateness of this prescription combination has already been vetted and nothing is presented to the pharmacist to alter the course of action in filling these prescriptions.

7. *Patient was dispensed an opioid and a benzodiazepine within 30 days*
8. *Patient was dispensed an opioid and a benzodiazepine on the same day, and both prescriptions were written by the same prescriber*

Similar to the holy trinity, the combination of opioids and benzodiazepine were not known to the typical community pharmacist to be a sign of potentially suspicious activity in 2006. As the opioid epidemic evolved, there were situations where this combination could be evidence of suspicious activity. However, because opioids and benzodiazepines have different clinical indications, the practice of dispensing these two medications to the same patient was not uncommon. This scenario still occurs regularly in practice today.

When dispensing these two medications, the primary concern of a pharmacist relates to the adverse side effects that a patient may experience when taking the medications at the same time.[67] When this scenario is presented to a pharmacist, the common response would be to discuss the potential drug interactions and adverse reactions the patient may experience if the medications are taken together. Notably, because the risk is created by taking the medications at the same time, Mr. Catizone's red flag for dispensing the medications within 30 days of one another is not in line with any known industry standard or "red flag" that I have encountered.

[67] U.S. Food & Drug Administration, "FDA requiring Boxed Warning updated to improve safe use of benzodiazepine drug class" (Sept. 23, 2020), available at https://www.fda.gov/drugs/drug-safety-and-availability/fda-requiring-boxed-warning-updated-improve-safe-use-benzodiazepine-drug-class.

This red flag computation would capture, for example, a prescription for a 2-day supply of benzodiazepine that was prescribed 28 days before a prescription of opioids. This combination does not, based on my experience or knowledge of industry standards, present circumstances amounting to a "red flag" requiring further consideration or action on its own.

9. *Patient was dispensed two short-acting (or immediate release) opioid drugs on the same day*

This computation was not considered a "red flag" that pharmacists were cautioned and taught to identify and resolve during the relevant time period. I can think of several scenarios where a patient could receive two different short acting opioids on the same day, for either non-concurrent use, or where the type of opioid or opioid combination drug would make clinical sense to combine with another short acting opioid for certain conditions. Therefore, I cannot agree that the presentation of two prescriptions of this nature at the same time would always be a "red flag".

10. *Patient was dispensed an opioid prescription of over 200 MME per day before 2018 or over 90 MME per day after January 1, 2018*

This computation of a "red flag" was not considered a red flag in 2006. As pharmacists' understanding of the opioid epidemic evolved, it eventually became known that high MME per day could be a warning that a prescription was illegitimate. The slow and continuous change in perception regarding MME per day is made evident by the fact that the CDC published guidance in 2016, 2019, and then again in 2022 on the issue. Prior to the 2016 publication, it was not common for community pharmacies or pharmacists to calculate or consider MME totals in their evaluation of dispensing practices and volumes. Further, even in circumstances where a patient was identified as receiving a high dose of MME per day, there are safety concerns with refusing to fill such a prescription as an improper opioid taper can cause opioid withdrawal, and could result in a trip to urgent care, the emergency room, or even death. An opioid taper takes many months and sometimes even years to achieve. For some patients, a taper may never achieve the 90 MME per day threshold. Accordingly, where a high dose of MME per day has been prescribed, a pharmacist must exercise the pharmacists' process of patient care, which would typically require the pharmacist to have a conversation with the patient and potentially the prescriber to identify whether a taper is being considered or has been initiated. A pharmacist alone cannot initiate a taper—it must be done in conjunction with the prescriber.

11. *An opioid was dispensed to at least 4 different patients on the same day, and the opioid prescriptions were for the same base drug, strength, and dosage form and were written by the same prescriber.*

This computation is not automatically considered a red flag during the relevant period. Notably, a pharmacist working the bench in a community pharmacy would often see multiple prescriptions from the same prescriber for the same base drug, strength and dosage form for various prescriptions. For example, a prescriber that is routinely performing the same procedure on their

patients will often prescribe the same base drug at the lowest strength and dose. A pharmacist is an expert in their region of practice, therefore awareness of such a situation is not uncommon. Accordingly, I disagree with Mr. Catizone that anytime a prescriber issues prescriptions of the same base drug, strength and dosage form to 4 or more patients on the same day, a pharmacist must be suspicious that the prescriptions are illegitimate.

12. *An opioid prescription was refilled more than 5 days before the patient's previous prescription should have run out.*

This computation is not always a red flag. There are clinical reasons why a patient may refill their prescription more than 5 days before the previous prescription should have run out. If a patient's pain is not controlled, an increase in dose would be warranted. Accordingly, the prescriber may have told the patient to increase their dose with the prior prescription before seeing the doctor for a follow-up appointment. In this case I would follow the pharmacists' patient care process to obtain more information and then I would exercise my best judgment in the totality of the circumstances and proceed with dispensing when appropriate.

13. *A patient was dispensed more than 210 "days of supply" of all opioids combined in a 6-month period.*

The 210 "days of supply" is an arbitrary number and is not an accepted red flag. While total "days of supply" of all opioids over an extended period of time can indicate suspicious circumstances, in my experience there is no rule, guideline, or common practice that dictates what the number of "days of supply" or period of time must be. Furthermore, there are various situations where such prescribing methods are routinely occurring for a given patient. For example, a patient that is prescribed a 6-month supply of long-acting opioids (180 "days of supply") may also be dispensed a short acting opioid for break through pain each month. When this occurs, the combined "days of supply" often exceeds 210 "days of supply" in a 6-month period.

14. A patient was dispensed an opioid and paid in cash

Paying in cash, on its own, is not always a reliable an indicator that a prescription is potentially illegitimate. There are numerous situations where a cash payment is not only justified, but may be the only option for a patient who is uninsured. When a patient presents an opioid prescription and indicates that they will be paying in cash, the pharmacist may be able to see that prior non-controlled prescriptions were paid for in cash. In this scenario, the payment in cash would not raise suspicion of a potentially illegitimate prescription for a typical pharmacist (absent other circumstances). If a pharmacist does not see any prior prescriptions for the patient in the computer, a pharmacist acting in the usual and customary practice would ask the patient if he or she has insurance. Their response content and behavior would influence whether the pharmacist believed that cash payment for this opioid was indicative of a potentially illegitimate prescription. Lastly, if a pharmacist saw or knew that the patient had insurance but was opting to pay for the opioid in cash, a pharmacist acting in line with the usual and customary practice would likely ask the patient why they were opting to pay in cash. The patient's response would inform whether the pharmacist determined that the circumstances gave rise to suspicion that the prescription was not legitimate, or if the patient gave a reasonable basis for opting to pay in cash. For example, I am aware of actual instances where a patient's copay for an opioid is higher than the cash price, such that it would be logical for the patient to elect not to use their insurance.

* * *

Critically, the presence of a red flag does not require automatic refusal to dispense. In fact, most times the "suspicious circumstances" or warning signs are easily resolved, sometimes just by looking at the prescriber's office or field of expertise, and other times with one or two simple questions to the patient. Then, the prescription is dispensed. Publix had appropriate policies in place reinforcing its expectations of pharmacists to exercise their corresponding responsibility and supporting their exercise of judgment in the context of evaluating "red flags."[68]

I am not aware of any reliable, peer reviewed study establishing an industry standard based number of legitimate prescriptions that one would expect to present with red flags of any type, let alone those created by Mr. Catizone. There is no basis for, and I fundamentally disagree with Mr. Catizone's unsupported attempt to assert any percentage-based conclusions with respect to the status of any population of Publix's dispensed prescriptions. Pharmacists are not charged with preventing the fill of prescriptions with *red flags*—rather, the goal and the standard is to prevent the dispensing of prescriptions known to be illegitimate.

B. The Pharmacy Industry Did Not Have a Requirement to Document Mr. Catizone's "Red Flags"

Documenting the presence of any facts indicating a prescription might not be for a legitimate purpose, or any due diligence done to inquire into those facts, is done at the discretion of each

[68] *See, e.g.*, Ottolino Dep. Ex. 1 (2011 Memo PUBLIX-MDLT8-00118914-15).

pharmacist. Companies do not set standards for how pharmacists practice and document patient care services. I disagree with Mr. Catizone's opinion that pharmacies like Publix should have required their pharmacists to document the presence or identification, the evaluation, and the resolution of "red flags." This is particularly true at the beginning of the relevant time period in 2006. In fact, in the scenarios listed above, I would typically not have documented any of the red flags. By dispensing the medication, a pharmacist is representing that they performed the pharmacists' process of care and the "Five Rights of Medication Administration" were followed. In my experience I, as well as my colleagues, infrequently documented the type of "red flag" information that Catizone describes in the computer system or on the hard copy prescription. It is not the industry standard to do so, and certainly was not in 2006. While there are circumstances warranting documentation on the prescription or in the dispensing software regarding the investigation of suspicious qualities of a prescription, those circumstances are rare.

The typical community pharmacy does not set rigid rules regarding the type and quality of information that pharmacists must document beyond what is expressly required by law. Nor do Georgia pharmacy regulators require such documentation.[69] For example, GDNA Director Dennis Troughton testified that GDNA does not have any policy, guidance, standards or rules about how pharmacists should document red flags because "red flags . . . [are] not . . . in the rule or the law."[70] Instead, they are "an educational tool provided that we chose at GDNA."[71]

The documents I have reviewed in this case provide insight that Publix pharmacists were indeed exercising their corresponding responsibility consistent with the standard of care. The documentation provided in the spreadsheet titled PUBLIX-MDLT8-00145543, is typical of the types of notes that pharmacists may document in the dispensing software. Within those notes, there is evidence that pharmacists were fulfilling their corresponding responsibility prior to dispensing controlled substances. They called prescribers, checked the PDMP and cleared red flags prior to dispensing controlled substances. Some examples of documentation that demonstrate this include the following:

PRES_DEA_NUM	FILL_DATE	PRODUCT_NAME	PATIENT_NOTE
BG4349646	8/29/2010	hydrocodone	ALWAYS CHECK GA DRUG MONITORING SITE BEFORE FILLING FOR THIS PATIENT
BG4349646	8/29/2010	hydrocodone / clonazepam	ON SCHEDULE PER THE WRITTEN RX AND I WOULD NOT REFILL EARLY; CONCERN OVER PT HIGH DOSE AND PT SAFETY WITH CONTROL SUBSTANCE AND MULTIPLE MED INTERACTIONS
BG4349646	08/29/2010	hydrocodone	PATIENT USES OUR PHARMACY + CVS + WALMART

[69] Kaptain Dep. at 80:6-18 ("I would not ask them to document it. I would just say they would need to be able to articulate it.").

[70] Troughton Dep. at 100:10-101:2.

[71] *Id*.

BM8634695	9/13/2010	oxycodone	CHECK PDMP---GETS MORPHINE AND XANAX AT WALMART---BEEN ON THESE DOSES ALL TOGETHER LONG TERM
BS3150644	9/15/2010	oxycontin	DL REDACTED - DRIVER'S LICENSE NUMBER DOB REDACTED - DOB EXP REDACTED - LICENSE EXPIRATION
AR8551916	12/09/2012	hydrocodone	REVIEW PROFILE WHEN FILLING CONTROLS
AP8696203	04/14/2012	hydrocodone	VERIFY CONTROLS!! PER DR. GRIFFITH
BP3782960	05/02/2013	cyclobenzaprine / diazepam	DR PARRY HAS D/C THIS PATIENT AS OF 7/13/16. NO REFILL REQUESTS AFTER THAT DATE.
BM6323492	6/20/2014	hydrocodone / alprazolam	CURRENTLY HAS MME/DAY OF 63. LEFT MESSAGE FOR EXACT DIAGNOSIS CODE AND VALIUM/OPIATE INTERACTION
BG7391282	8/3/2017	oxycodone	CHRONIC PAIN DX M54.16
BT0275001	11/14/2018	methadone	CUSTOMER BROUGHT IN RX FOR METHADONE ON 3/6/16 --- I GAVE HIM RX BACK - IN THE PAST, HE HAS ACCUSED ME AND THIS PHARMACY OF STEALING HIS MEDICATIONS - I DO NOT FEEL COMFORTABLE FILLING HIS MEDICATIONS - IN THE PAST, I HAVE EVEN COUNTED THE PRESCRIPTIONS IN FRONT OF HIM - AND THERE ARE STILL ISSUES

As I read through the notes, it is apparent that pharmacists are exercising their clinical knowledge regarding patient safety concerns for opioids. Several notes cited that the PDMP should be checked prior to dispensing. There are even notes concerning early refills and refusal to fill, as well as documentation of an MME calculation. These notes are typical of community pharmacists. The note dated June 20, 2014 (BM6323492) is quite impressive considering the MME literature first became part of the CDC guideline in 2016.[72] This suggests that pharmacists were staying up to date on the clinical knowledge of opioids and Publix hired pharmacists with excellent clinical judgement.

The fact that each opioid description matching one of Mr. Catizone's flags does not have a note, or a note relevant to controlled substance due diligence, is not surprising or concerning. First, Mr. Catizone's "red flags" are not all, nor always, actually "red flags" as discussed above. Second, even where an actual flag or indicator is present that a prescription might not be for a legitimate purpose, the custom and practice of community pharmacists is only to document in the situations

[72] CDC Morbidity and Mortality Weekly Report (March 18, 2016), https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm#print

where they cannot otherwise easily resolve or easily refuse the prescription without making any notes.

C. The Standard of Care for Pharmacists in Georgia Does Not Require Them to Check the PDMP for Every Controlled Substance Prescription

Mr. Catizone's opinion that PDMP must be used for every controlled substance is not only inconsistent with the standard of care, but inconsistent with Georgia law. As previously explained, there is no requirement under Georgia law for pharmacists to check the PDMP prior to dispensing a controlled substance prescription. Pharmacists are required only to enter prescription information for Schedule II-V controlled substances within 24 hours.[73]

Furthermore, I reviewed the email chain that Mr. Catizone relies on for his assertion that it is "not the norm" for Publix pharmacists to check PDMP for each controlled substance.[74] Mr. Chavez's statement that the determination to use PDMP is made by the individual pharmacist and that may often include new patients or "specific meds" is in line with not only Georgia law, but the usual and customary practice of pharmacists in states that do not require mandatory checks. The fact that it is not the norm to check every single controlled substance (including non-opioids) does not indicate anything other than alignment with Georgia law.

D. Publix Did Have Store Monitoring Practices and Programs

My review of Publix deposition testimony and documents and my interviews with Lindsay Burckhalter and Leigh Anne Jacobson confirmed that Publix had store monitoring practices and programs that analyzed the controlled substance dispensing practices of individual stores. Since at least 2006, Publix pharmacy supervisors visited their assigned stores and also had frequent phone calls with the pharmacists in those stores. Both Lindsay Burckhalter and Leigh Anne Jacobson confirmed that supervisor store visits and communications regularly involved a review of both hard copy and electronic prescription information for controlled substances, including opioids. Supervisors would go over dispensing decisions with pharmacists, verifying the information that the pharmacists used to exercise their professional judgment and dispense the prescription. Supervisors would give pharmacists feedback and instruction on the types of patient or prescriber scenarios that might indicate a prescription could not be for a legitimate purpose. Documents I reviewed confirmed that pharmacy supervisors did substantive reviews of store information or statistics regarding opioids and vetted any change in quantity or type of opioids dispensed at their stores.[75]

In 2012, Publix started providing supervisors with CII Pull Reports, coincident with regulators and the industry's evolving focus beyond prescription fraud/forgeries. These reports provided

[73] Ga. Sec. of State, Prescription Drug Monitoring Program, Ga. HB 249, available at https://sos.ga.gov/how-to-guide/prescription-drug-monitoring-program.

[74] March 13-14, 2019 email chain regarding PDMP checks (PUBLIX-MDLT8-00074321, P-PUB-0599)

[75] 2008 email exchange between C. Hewell and D. Richardson, Atlanta Division Supervisor (PUBLIX-MDLT8-00073507-08); 2011 email exchange between C. Hewell and J. Layton, Atlanta Division Supervisor (PUBLIX-MDLT8-00065743).

pharmacy supervisors with various metrics to monitor Schedule II prescriptions, including script counts for certain higher strengths of opioids and the percent of dispensed prescriptions at each store that were C-IIs.[76] According to Lindsay Burckhalter's deposition testimony and my interviews with her and Leigh Anne Jacobson, Publix used its C-II Pull reports to, among other things, identify if a particular store was among the top stores at Publix in any of these metrics.[77] Where a store was among the top stores at Publix or the store's figures otherwise seemed out of line with the Publix average or the store's previous metrics, the supervisor would investigate the underlying dispensing with the store at issue.[78] Leigh Anne Jacobson made clear in my interview of her that supervisors took this job seriously and would take the CII Pull Report with them to meet with or talk to pharmacy employees and follow up on particular metrics to determine if proper dispensing practices were being followed and if any additional education or training was required for the pharmacists at that store, or if any other action was needed.

E. I Did Not Find Any Support for the Idea That There Were Staffing Shortages in Publix Pharmacies Which Would Have Incentivized Pharmacists to Rush Through Controlled Substance Dispensing

Upon my review, Publix provided a work environment conducive to allowing pharmacists to use their professional judgment to make the best decisions for their patients. Based on the deposition of Ottolino[79], pharmacists were given adequate resources including personnel, time, and references to make sound decisions.[80] The resources (personnel, time and references) available to them met the industry standard. During a time when many pharmacies had pharmacist and technician turnover and were denied extra hours for technician help, that was not Publix's experience. They had loyal employees with supportive administrative supervisors who were always licensed pharmacists. Their work environment met industry standard for this time, and the documents and testimony reflect that Publix pharmacists had the tools and resources needed to do their jobs. Publix even conducted a time and motion study to ensure that adequate personnel were available at its pharmacies.[81] During a time when the pharmacy industry was shifting to demand their pharmacists to fill more prescriptions at a faster pace, there was no evidence of Publix changing its culture to do the same. During this time, while many pharmacies were adding drive-thru locations to their businesses, most Publix stores (22 out of 25) in Cobb County did not.

I reviewed Mr. Catizone's report. He offers some opinions that Publix was understaffed during the relevant time period. I reviewed the documents that he relies on in support of these opinions.

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[76] CII Pull Report (February 2021) (PUBLIX-MDLT8-00092942); CII Pull Report (August 2012) (PUBLIX-MDLT8-00122981).

[77] Burckhalter Dep. at 88:3-22.

[78] *Id*.

[79] Ottolino Dep. at 51:15-53:13.

[80] *See also* Nov. 15, 2007 Ottolino email requiring pharmacist overlap (PUBLIX-MDLT8-00039827).

[81] Ottolino Dep. at 262:24-266:9.

Two of these documents were customer complaints from 2017 about the same store.[82] While it is unclear what exactly happened in this situation there are no other complaints identified by Mr. Catizone for any other stores during any other periods. Based on my experience, one cannot reasonably or reliably infer what staffing problems, if any, were present across Cobb County Publix pharmacists during across all times based solely on two customers' complaints from the same year relating to a single location.

I reviewed the other documents cited by Mr. Catizone in support of this opinion, and they are all from March 2020 and later, all around the height of the COVID-19 pandemic. Based on my experience, I am aware that staffing was a problem for pharmacies generally during this period, and this problem was compounded by the need to provide vaccinations and COVID tests with patient counseling. Furthermore, based upon my experience, staffing shortages occurring during the COVID-19 pandemic are not indicative of staffing shortages at any other time prior to the pandemic. I have not seen anything in the materials that I have reviewed, including the materials cited by Mr. Catizone, that indicate that Publix was understaffed or that its pharmacists were unable to exercise their professional judgment or to take the necessary time to review prescriptions.

F. The Industry Typically Compensates Pharmacists Based on Store or Pharmacy Performance Which Would Include Controlled Substances

My review of Mr. Catizone's Reports and his testimony indicate that he believes that compensating or bonusing pharmacists in any way tied to overall drug sales or profitability is not in line with the pharmacy industry standard of care. I disagree with that conclusion. In my experience, it is common for compensation or bonuses to be tied to the profitability or sales of the pharmacy department, including profit from controlled substances. Further, it is my experience that the usual custom and practice of pharmacists is not to focus on or even be aware of how bonuses are calculated nor to be incentivized in any way to fill certain prescriptions over others to generate more profit. The pharmacists do not control the prescriptions that are presented to their counter – they simply evaluate (and where appropriate fill) the next in line.

When I fill a medication for a patient, as a pharmacist I am not concerned about a bonus payment that I may receive. This never enters my mind. I wholeheartedly disagree with Dr. Lembke when she testifies that she believes bonuses for pharmacists influence their decisions to dispense. That is not my personal experience or the experience of Publix's pharmacists based upon their deposition testimony.[83] I am taking care of the patient in front of me and making sure that the medication is best for them. I am not thinking about a bonus. When I worked as a community pharmacist, my primary compensation was salary-based, and I was eligible for a bonus based in

[82] Catizone General Report at 71; King Dep., Exs. 38 (February 20, 2017 customer complaint, PUBLIX-MDLT8-00092609-10) and 39 (February 17, 2017 customer complaint, PUBLIX-MDLT8-00092606-07); Jacobson Dep. at 348:17-351:1, and Ex. 40 (February 17, 2017 customer complaint, PUBLIX-MDLT8-00092604-05).

[83] Deposition of Shannon Brice at 335:20-336:20; Deposition of Deanna Bunch at 105:7-19; Burckhalter Dep. at 156:14-158:9; Deposition of Erika Owens ("Owens Dep") at 203:16-204:2; Deposition of Toan Do at 252:8-22.

part on amount of pharmacy sales and profitability. That program was similar to the structure of the Publix pharmacist compensation and bonus program that I learned of through the Quarterly Retail Bonus Plan policy[84] and conversation with Lindsay Burckhalter. When I did receive a bonus from my employer, I assumed it was based on a job well done and meeting goals, such as inventory and immunizations, and was not focused on the very small portion of my compensation that might come from the sale of a given medication.

6. Compensation

I am compensated at a rate of $600.00 per hour for all work performed in preparing this report and for any testimony in this case at deposition or trial.

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Based on the information that I've reviewed, as well as my knowledge and experience as a pharmacist, clinical professor, and researcher, Publix met its obligations to institute effective diversion control programs in Cobb County and maintained effective controls against the diversion of opioid medications during the applicable time period. Publix's policies and procedures were appropriate to support their pharmacists in the exercise of corresponding responsibility with respect to evaluating and dispensing opioid prescriptions.

Professionally,

/s/ Stefanie Ferreri
Stefanie Ferreri

[84] Owens Dep., Ex. 6 (Quarterly Retail Bonus Plan, PUBLIC-MDLT8-00059249-50).